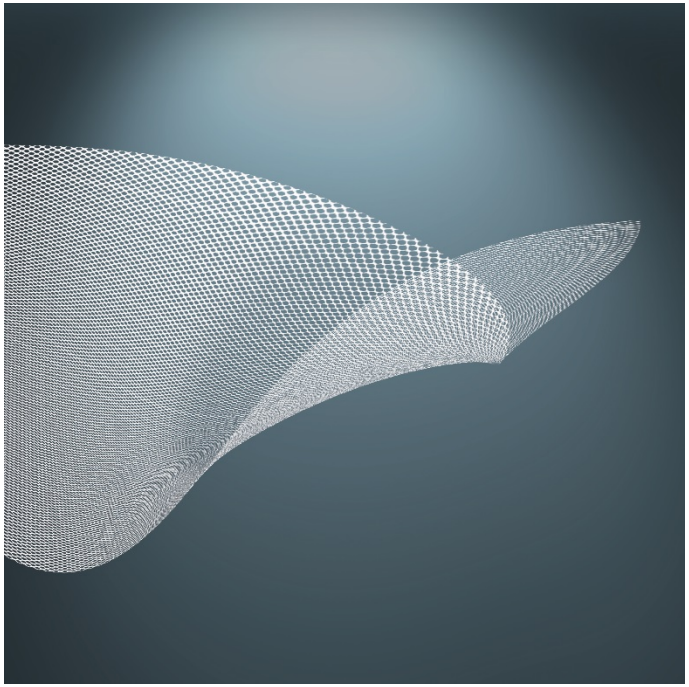


4DMESH® STUDY
2 years results

A Dabrowski P Tiry JF Gillion
Et le Club Hernie
MESH Paris 17/06/2016

STUDY DESIGN

Observational, national, multicentre, non-comparative with descriptive purpose

Main objective: Assess the incidence and the severity of chronic postoperative pain at 1 year in patients who have a 4DMESH® implant, in current conditions of use.

Primary endpoint:

Early and late postoperative chronic pain at 1 month and 1 year:
Visual Analogical Scale (VAS)

Secondary objectives: Assess the effectiveness and the safety of the device estimating the per and postoperative complication rate.

Secondary endpoints:

Recurrences and postoperative complications at 1 month and 1 year,
The operative time,
Prosthesis handling,
Recovery of physical, sports and professional activities.

SELECTION CRITERIA

Inclusion criteria

Patients ≥ 18 years

Patients with:

- inguinal or femoral hernia,
- unilateral or bilateral hernia,
- primary hernia.

Signed Informed consent form.

Exclusion criteria

Emergency surgical procedure,

Strangulated or recurrent hernia,

Infection on the surgical site,

BMI greater than 40kg/m^2,

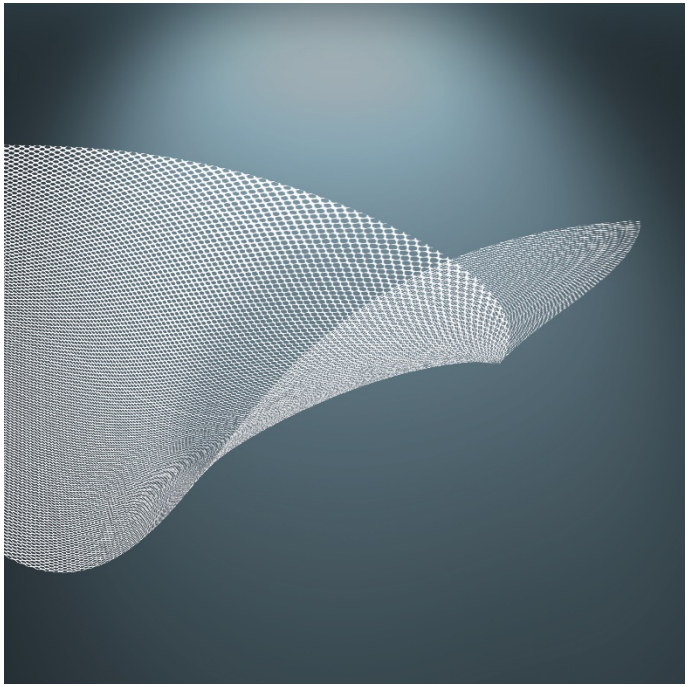
Analgesic-chronic treatments, anticoagulants,

Allergy to one of the device components,

Contraindication to general or local anesthesia,

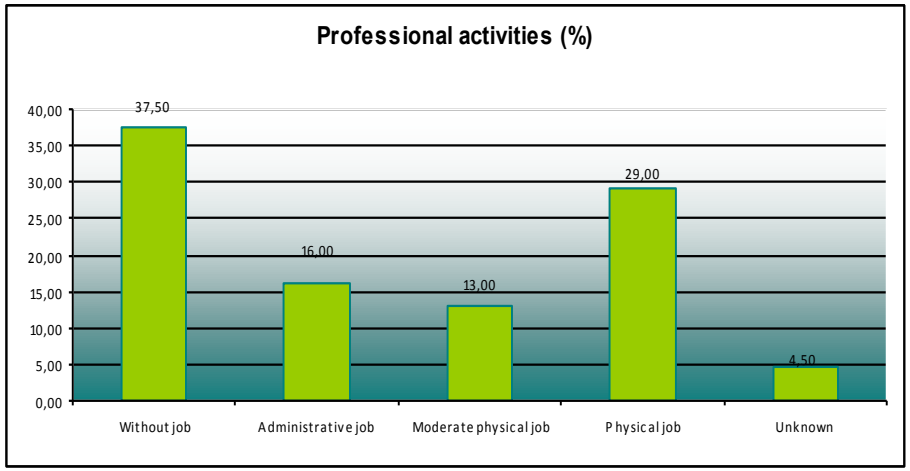
Pregnant patient.

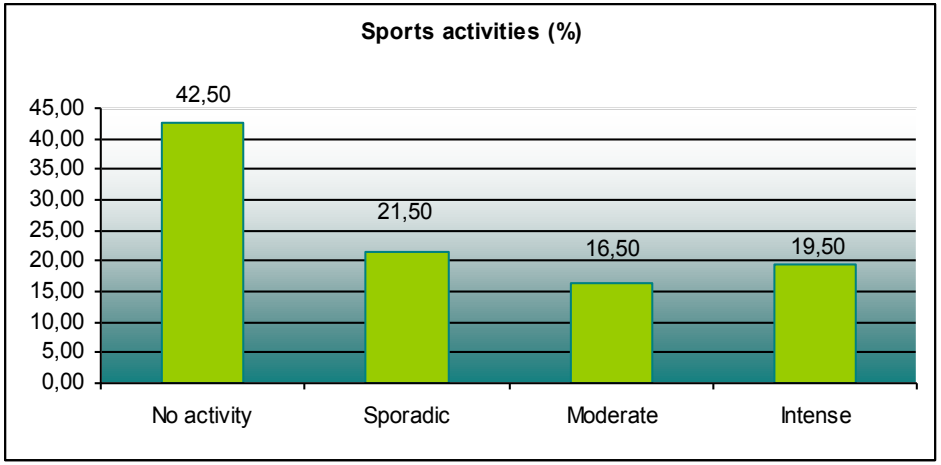
4DMESH® STUDY
Final results.



STUDY POPULATION

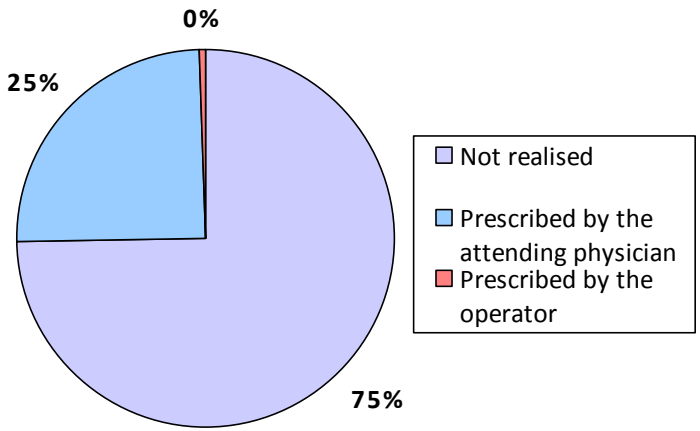
- 200 patients included and followed between 12 and 24 months
- Men 95%, women 5%
- Average age: 57.6 years (min. 20, max. 91)
- BMI between 19.33 km/m² and 35.18 kg/m²
- Never smoked, stopped or occasional smoker 85.9%, daily smoker 14.1%



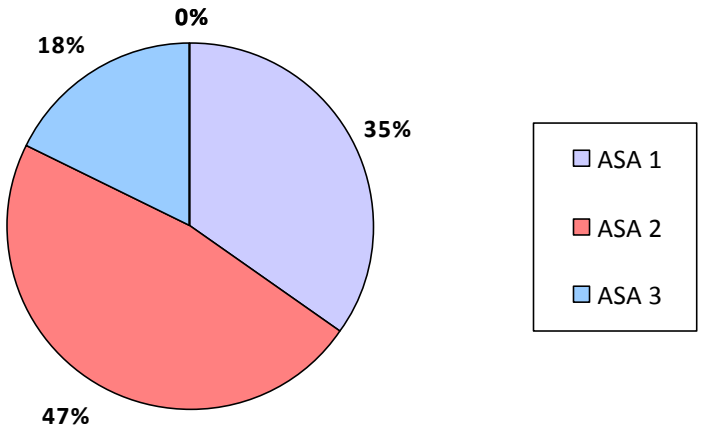


STUDY POPULATION (3)

- Echo-parietal indication



- ASA



Pre operative data

Risk factors

Abdominal pressure	%
No	71.7
Chronic cough	9.6
Dysuria	4.5
Hard working	1
Intense sport activity	15.1
Ascitic	0

Healing	%
No	81.5
Diabetes	2.1
Corticoids	1.6
Pelvic radiotherapy	0.5
Chemotherapy	1.1
Antiaggregation therapy	12.2

Dissection	%
No	70.7
Mac Burney	13.7
Intraperitoneal surgery history	10.7
Extraperitoneal surgery history	3.1
Prostatectomy history	1.0
Adenomectomy history	0.5

ASA	%
ASA 1	45,2
ASA 2	39,2
ASA 3	15,6
ASA 4	0,00
ASA 5	0,00

Pre operative data

Hernia

Hernia history

- **No hernia history, 71.3%**
- With personal history of hernia, 23.6%
- Familial history of hernia, 5.1%

- **Primary hernia, 95.9%**
- 1 recurrence, 3%
- 2 recurrences, 1.1%

Characteristics of the hernia

- Palpable swelling, 4.0 %
- **Inguinal swelling, 74.9%**
- Inguino funicular swelling, 14.6%
- Inguino scrotal swelling, 6.0%
- Femoral swelling, 0.5%

Bilateral hernia repair

- No , 3.5 %
- **Bilateral hernia unknown, 43.0%**
- Lateral hernia already undergone, 14.0%
- Lateral hernia overlooked, 0.5%
- Deferred hernia repair , 0.5%
- **Yes , 31.7%**
- Bilateral hernia known before surgery, 5.5%
- Bilateral hernia diagnosed during pre-op visit, 1,0%
- Bilateral hernia repair of principal, 0%

Symptoms and disorders

Symptoms

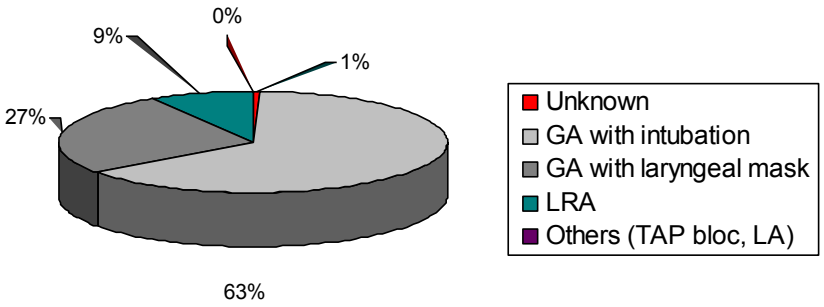
- Asymptomatic hernia, 6.5%
- **Discomfort, pain and dysesthesia, 87.4%**
- Infatuated hernia, 5.5%
- Others (strangulated hernia), 0.5%

Disorders

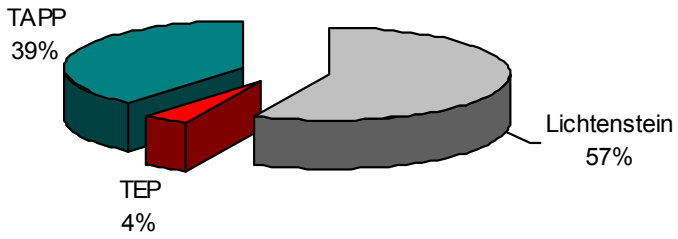
- No , 6.1 %
- **Discomfort, 37.6%**
- Tingling, 0.5%
- Decreased sensitivity, 0 %
- Loss of sensitivity , 0.5%
- **Moderate pain , 26.4%**
- **Significant pain, 28.9%**
- Others (Chronic lower back pain, headaches, psychotic disorders), 0%

SURGERY

Anesthesia

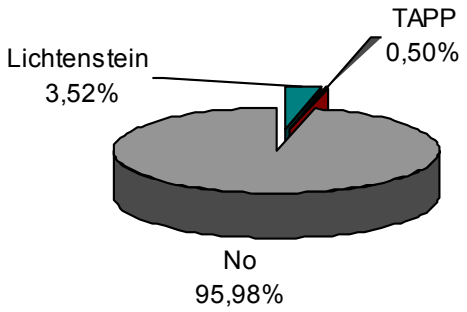


surgical technique



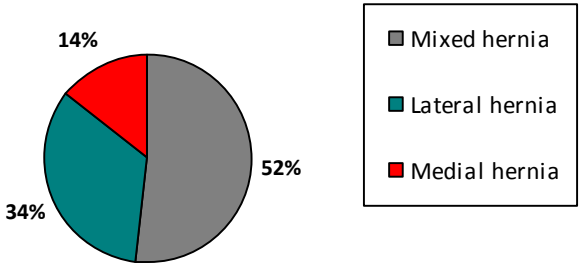
Associated surgical step (Lichtenstein)	%
Resected hernia sac	45,69
Non resected hernia sac	**54,31**
Transversalis Fascia approximation	8,66

Conversion to another surgery

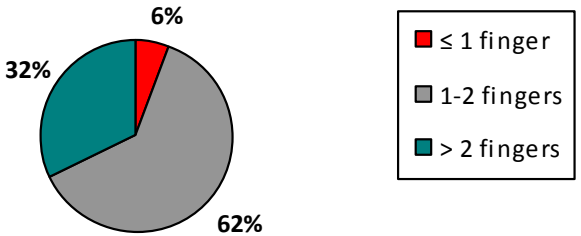


Type of hernia

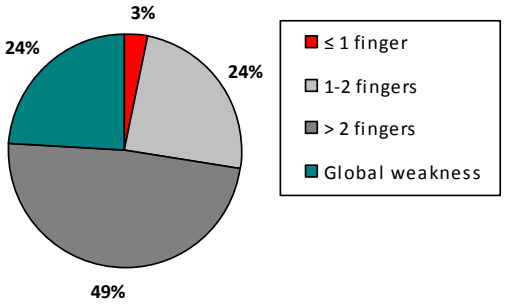
Type of hernia



Lateral hernia



Medial hernia



SURGERY (2)

Operative duration (minutes)

LICHTENSTEIN			LAPAROSCOPY		
Minimum	**Average**	Maximum	Minimum	**Average**	Maximum
10	**24.18**	65	12	**22.34**	40

Average mesh placement time

LICHTENSTEIN			TEP			TAPP		
Minimum	**Average**	Maximum	Minimum	**Average**	Maximum	Minimum	**Average**	Maximum
2	**10.47**	26	5	**14.6**	24	2	**12.15**	35

Prosthesis fixed in:

70,87% with staples for the Lichtenstein technique

94,67% with resorbable staples for the TAPP/TEP technique

Mesh Handling

Lichtenstein

Flexibility

98.88 % satisfying

Shape memory

88.76 % satisfying

Insertion

90.0% satisfying

Laparotomy TEP

Flexibility

100 % satisfying

Shape memory

100% satisfying

Insertion

100 % satisfying

Laparotomy TAP

Flexibility

98.3 % satisfying

Shape memory

96.66 % satisfying

Insertion

100 % satisfying

Per operative events

Lichtenstein

No , 97.36 %

1 Peritoneal gap.

1 Difficulty for exposition.

Laparotomy TEP

No , 75 %

2 Peritoneal gap.

Laparotomy TAP

No , 100 %

Early post operative complications

Surgery site complications

No , 92.9 %

9 Subcutaneous abscess without infection.

2 Periprosthetic abscess without infection.

Out surgery site complications

No , 97.5 %

1 Homolateral Hydrocele

Medical complications

No , 95.5 %

3 Phlebitis, lymphangitis,

1 Urinary retention,

1 Bronchopulmonary

Clavien graduation

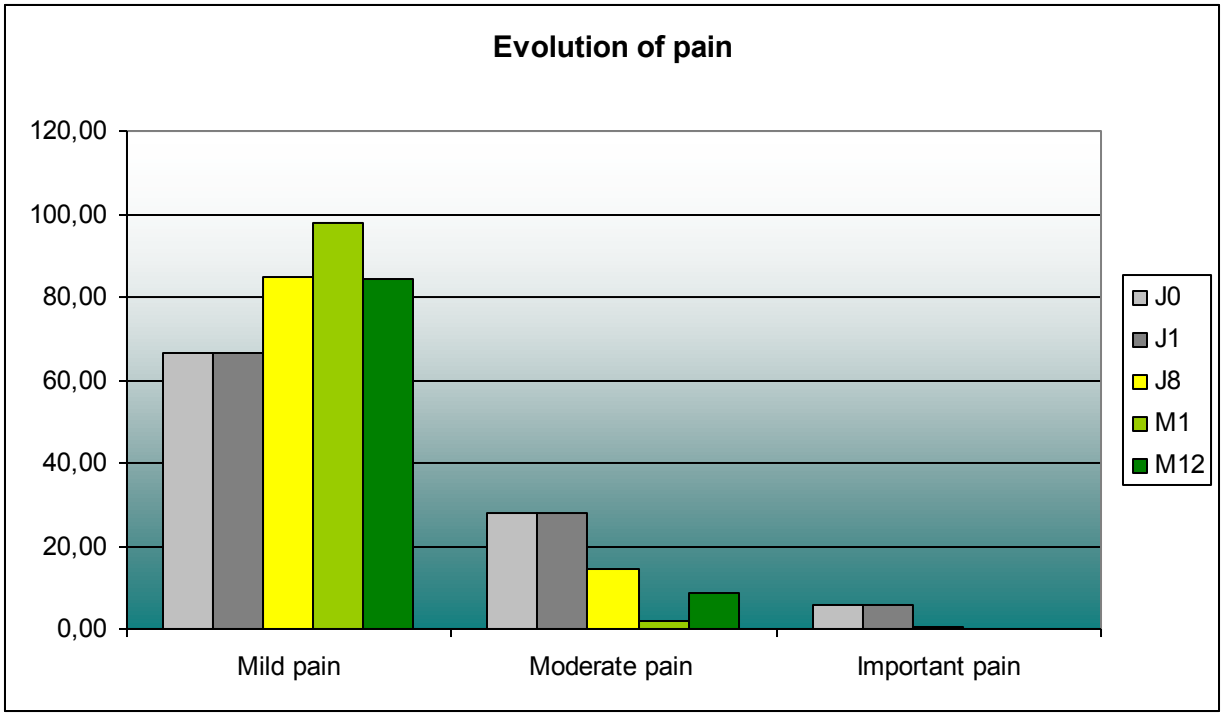
Grade 0, **96.9 %**

Grade I, **2.56%**

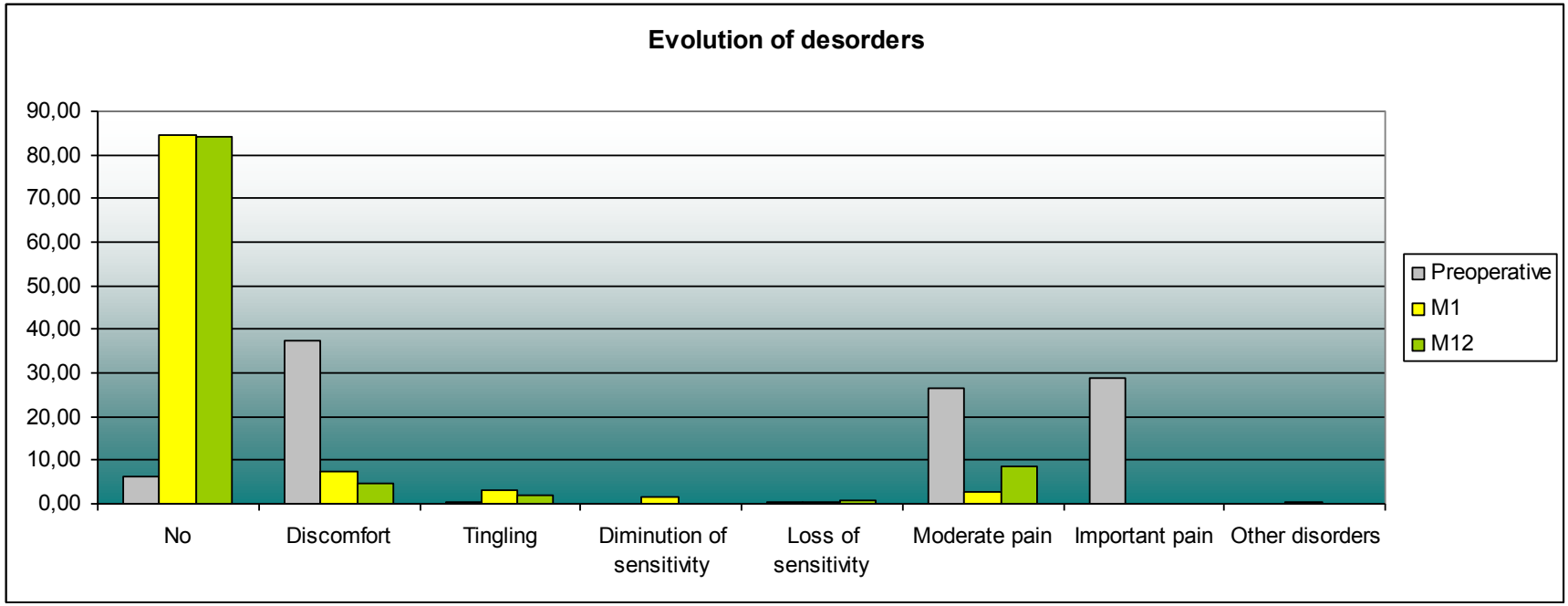
Grade II, **0.51%**

Grade III, IV, V, **0%**

POSTOPERATIVE FOLLOW-UP



POSTOPERATIVE FOLLOW-UP



No reoperation

No recurrence.

POSTOPERATIVE FOLLOW-UP

Patient's feeling